REMARKS

Claims 1-4 remain active for examination. Applicant acknowledges with appreciation that the Examiner has accepted Applicant's explanation that Group I and Group II claims do not define independent and distinct inventions.

The amendments to claims 1 and 3 are submitted to further clarify the language related to dosage amount in claims 1 and 3 to consistently recite "initial effective dosage amount" to make the claims read more clearly. The amendments also help clarify that the initial effective dosage amount is determined by the maximum amount to achieve maximum skin rest. Support for the amendments is found within the specification on page 4, line 20 to page 5, line 1.

Applicant has amended the language in claims 1 and 3 to clarify that more than one administration of the neurotoxin composition is required to carry out the method of the invention. Support for more than one administration of the neurotoxin composition is found within the specification at page 3, lines 2-9.

The Examiner, in an Office Action mailed on October 8, 2007, rejected all 4 pending claims in the application.

A. Claims 1 and 3 were rejected under 35 U.S.C. § 112 (2nd) as being indefinite for failing to particularly point out and distinctly define "effective amount".

B. Claims 1-4 were rejected under 35 U.S.C. § 102(e) as being anticipated by Donovan U.S. Patent Application 2004/009180 ("Donovan").

C. The Examiner also rejected claims 1-4 under 35 U.S.C. § 103(a) as being unpatentable over Hanin et al U.S. Patent 7,140,371 ("Hanin III").

Applicant respectfully traverses the Examiner's 35 U.S.C. § 112 (2nd), 102(e), and 103(a) rejections of claims 1-4 and requests reconsideration and withdrawal of the rejections based on the following remarks.

A. Claims 1 and 3 rejected under 35 U.S.C. § 112 (2nd) as being indefinite.

The Examiner appears to assert that the phrase "effective amount" in claims

1 and 3 is vague and indefinite because it is unclear as to whether the effective dosage amount is dependent upon the amount required to reduce the appearance of facial wrinkles or to rest the skin.

Applicant has amended the language related to dosage amount in the claims to consistently recite "initial effective dosage amount" to make the claims read more clearly. Applicant has amended claims 1 and 3 to further clarify that the said "initial effective dosage amount" is determined by the amount of neurotoxin composition required to achieve maximum skin rest based on the patient's diagnostic profile. Maximally rested skin allows for more normal motion to be achieved. Support for the submitted amendments is found within the specification at page 4, line 20 to page 5, line 3.

In summary, Applicant asserts that the amendments to claims 1 and 3 more distinctly express what Applicant regards as his invention. Applicant respectfully requests that the Examiner withdraw the rejection of claims 1and 3 as indefinite and allow the amended claims.

B. Claims 1-4 rejected under 35 U.S.C. § 102(e) as being anticipated by Donovan

Donovan discloses that a patient may be treated with botulinum toxin type A and obtain a reduction in forehead wrinkles. The effect lasts for about four months. No additional or multiple treatments are disclosed. The Examiner asserts that the reduction to "zero" treatment of the toxin is a "decreased amount" for subsequent treatments and is not excluded by the Applicant's invention as claimed.

Donovan does not describe multiple treatments with botulinum toxin type A to reduce wrinkles. Donovan discloses a variety of mechanisms for introducing therapeutically effective amounts of neurotoxins to the skin of a patient to cause a therapeutic effect without undesirable pain. Topical applications, transdermal patches, skin abrasion techniques, ultrasound, and electrical stimulations are among the methods disclosed for introducing a neurotoxin to the patient's skin. The treatment of wrinkles is disclosed as one of several possible therapeutic effects. However, the application of each neurotoxin is taught to be a single application.

The claims of the instant application inherently require a minimum of two treatments with a neurotoxin composition. Claims 1 and 3 recite that the patient is

administered an initial effective dosage amount of the neurotoxin composition. Claims 1 and 3 further recite that at least one additional incrementally decreasing amount of the neurotoxin is administered to the patient. Thus, at least two treatments are required for the method as claimed. Therefore, "zero" or no administration after the first treatment is not within the scope of Applicant's invention as claimed.

Furthermore, Applicant discloses and claims a method comprising acquiring a diagnostic profile, determining an initial effective dosage amount of a neurotoxin, administering the initial dosage amount, and administering at least one or more additional decreased dosage amounts of the neurotoxin. Donovan does not disclose this claimed method. Furthermore, Donovan does not describe a method wherein a neurotoxin is applied to a patient's skin to achieve maximum skin rest.

Applicant respectfully requests that the Examiner withdraw the anticipation rejection of claims 1-4 and allow the amended claims.

C. Claims 1-4 rejected under 35 U.S.C. § 103(a) as being obvious over Hanin III

The Examiner's Action states "Hanin is supported by priority disclosures dating back to March 14, 2002." (Page 7, line 6, of the Action of October 18, 2007). Applicant respectfully traverses that proposition.

A U.S. patent may be used to show that claimed subject matter is obvious as of its filing date. See *Hazeltine Research v. Brenner,* 382 U.S. 252, 147 USPQ 429 (1965). However, the filing date of the patent must antedate the present application in order to be considered "prior art."

The Examiner has cited the Hanin III patent as prior art. Since Hanin III was filed on November 3, 2005, well after the present application, there would need to be some other basis than that filing date to assert that it is prior art to the present application. The Hanin III patent states that it is a continuation-in-part of U.S. Patent Application 10/663,041 ("Hanin II"), filed September 15, 2003, which is a continuation-in-part of U.S. Patent Application 10/099,602 ("Hanin I"), filed March 14, 2002.

Applicant's present patent application was filed September 5, 2003, before Hanin III and even before Hanin II.

Applicant acknowledges that Hanin I has a filing date earlier than Applicant's filing date and may be used as prior art against the present application under 35 U.S.C. § 102(e). However Hanin II was a **continuation-in-part** of Hanin I, so it contains new matter with respect to the disclosure of Hanin I. Hanin III was a **continuation-in-part** of Hanin II, so it contains new matter with respect to the disclosure of Hanin II and even more new matter with respect to the disclosure of Hanin I. Clearly the Examiner may not rely on any disclosures within Hanin II and Hanin III that were added or are new matter relative to Hanin I.

As stated by the Court of Customs and Patent Appeals:

"If ... the PTO wishes to utilize against an applicant a part of that patent disclosure found in an application filed earlier than the date of the application which became the patent, it must demonstrate that the earlier-filed application contains §§ 120/112 support for the invention claimed in the reference patent....Without such support, the invention, and its accompanying disclosure, cannot be regarded as prior art as of that filing date." – [*In re Wertheim*, 646 F.2d 527, 535–39, 209 U.S.P.Q. (BNA) 554 (C.C.P.A. 1981). See also *Ex Parte Ashkenazi et al*, 2005 WL 3694317 (Bd. Pat. App. & Interf.), 80 U.S.P.Q.2d 1753 and *Ex parte Ebata*, 1991 WL 326561 (Bd. Pat. App. & Interf.), 19 U.S.P.Q.2d 1952.]

Applicant traverses the Examiner's rejection of claims on the basis of Hanin III because it is not prior art to the present application. The Examiner seems to have assumed that all pertinent cited parts of the disclosure of Hanin III are contained within the priority document Hanin I. That is not correct. Applicant points out that the following passages from Hanin III, cited by the Examiner in this rejection, are new matter in Hanin III and are not present in the priority documents Hanin I and Hanin II:

col. 10, lines 63-65 (not present in either Hanin I or Hanin II)

col. 14, lines 58-62 (ditto)

col. 16, lines 8-23 (ditto)

col. 16, lines 38-42 (ditto)

col. 17, lines 58-62 (ditto)

col. 22, Example 4 (present in Hanin II but not Hanin I)

The following passages from Hanin III, also cited by the Examiner in this rejection, are present Hanin I:

col. 10, lines 55-63

col. 17, lines 52-57

Applicant submits that the Examiner inappropriately cited passages from

Hanin III that are not prior art to the present application.

However, the Examiner has referenced back to priority document Hanin I, which has issued as U.S. Patent 6,688,311. Applicant acknowledges that U.S. Patent 6,688,311 (Hanin I) is prior art and could be cited against the present application. In order to expedite prosecution, Applicant will now explain why Hanin I does not make obvious the subject matter of Applicant's claims.

Hanin I discloses a method for quantifying the paralytic effect of toxins on muscles. The focus of the disclosure is to determine the causal connection between the paralytic effect of a toxin upon a muscle and change in facial topography. Facial muscles are just an easier medium to measure such responses. See Hanin I at col. 6, lines 6-22. The examples in the patent of Hanin I are all directed toward determining the onset, peak, and duration of the paralytic effect of the toxins upon muscles. See Hanin I at col. 10, lines 63-67; col. 12, lines 50-53; and col. 13, lines 43-46.

There is no discussion in Hanin I of a method to maximally allow skin to rest via multiple injections of a toxin over an extended period of time. There is no suggestion of a method that comprises administering successively smaller multiple doses of a neurotoxin to patients. There is no suggestion that successively reducing the amount of neurotoxins administered over multiple injections would allow treated patients to experience longer lasting normal expression.

One of ordinary skill in the art would not have deduced from Hanin I the method and treatment regimen to allow skin to be maximally rested as hereby claimed by Applicant. Hanin I discloses methods of measuring skin responses to toxins. Hanin I does not suggest that administering of toxins to skins aids in resting the skin and allowing recuperation. Applicant's invention is concerned with methods of treating skin of patients for the patient's benefit. Hanin I is concerned with using the subjects to generate measurement test data for quantifying a patient's response to toxin exposure.

In summary, Applicant asserts that the disclosure of Hanin I, not of Hanin III, is the only prior art that the Examiner may use against the present claims. Hanin I does not disclose a method for multiple treatments of skin with a neurotoxin. The Applicant further asserts that, from the disclosure of Hanin I, it

would not be obvious to one of ordinary skill in the art to perform a method that comprises multiple administration of a neurotoxin to skin to maximize rest of skin.

Applicant respectfully requests that the Examiner withdraw the obviousness rejection of claims 1-4 and allow the amended claims.

CONCLUSION

Applicant submits that claims 1-4 as amended are allowable and requests the Examiner to allow the application to issue. If the Examiner has any questions, he is invited to phone applicant's undersigned attorneys.

Respectfully submitted: March 17, 2008

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